

## **REMARKS**

### **FORMAL MATTERS:**

Claims 1-42 were pending in the application. Claims 3, 4, 10, 11 and 20-42 were withdrawn from consideration. Claims 1, 2, 5-9 and 12-19 were examined and rejected.

By this Amendment, Claim 6 has been amended to recite that the bifurcated configuration is for positioning a free margin of the prolapsing leaflet as supported in paragraph [0049] and Figure 4B of the specification. Claim 7 has been amended by replacing “which extends” with “configured to extend” as supported in the specification at paragraph [[0051]] and Figure 5. Claim 18 has been amended to recite “fixation means for affixing” in order to clarify the function of the fixation means. Support for this amendment may be found throughout the specification, in particular at paragraph [0050]. Accordingly, no new matter has been added. Claims 14 and 20-42 have been canceled.

Claims 1-13 and 15-19 are pending after entry of the amendments set forth herein; however, claims 3, 4, 10 and 11 remain withdrawn from consideration.

### **REJECTIONS UNDER §112, ¶2**

Claim 18 has been rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner asserts that “fixation” and “attaching” are considered synonymous and further suggests deleting one “fixation” since “means for attaching” is used in Claim 19.

In response, the applicant notes that Claim 19 recites “fixation means” and not “means for attaching” as asserted by the Examiner. Accordingly, Claim 18 has been amended by replacing “attaching” with “affixing” to further clarify the function of the fixation means. Accordingly, this rejection may be withdrawn.

### **REJECTIONS UNDER §101**

Claims 6 and 7 have been rejected under 35 U.S.C. §101 because the claimed invention is allegedly directed to non-statutory matter. In view of the above amendments, the Applicant requests withdrawal of this rejection.

Claim 14 has been rejected under 35 U.S.C. §101 because the disclosed invention is allegedly inoperative and therefore lacks utility. As Claim 14 has been canceled, this rejection has been rendered moot.

#### **REJECTIONS UNDER §102**

Claims 1, 2, 5, 7-9, 12, and 16-19 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Streeter (US 2002/065554).

The claims are directed to implantable devices and systems for repairing a regurgitant cardiac valve having two or more leaflets and a subvalvular structure wherein at least one leaflet has a prolapsing segment, which comprises a structure for attachment to the prolapsing leaflet. The structure defines a coaptation surface against which an opposing leaflet coapts (i.e., not the one to which the structure is attached) during systolic contraction of the heart whereby the coaptation between the leaflets is normalized.

Streeter fails to disclose, teach or suggest a structure which attaches to the prolapsing leaflet. Streeter's apparatus is adapted to be affixed to the annulus of a cardiac valve but not to the prolapsing. Accordingly, Streeter does not anticipate or make obvious the claimed subject matter. Withdrawal of the rejection and allowance of claims 1, 2, 5, 7-9, 12, and 16-19 are respectfully requested.

Furthermore, claims 1, 5, 6, and 15 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Gabbay (US 6,419,695).

As set forth above, the present claims are directed to implantable devices and systems for repairing a regurgitant cardiac valve having two or more leaflets and a subvalvular structure wherein at least one leaflet has a prolapsing segment, which comprises a structure for attachment to the prolapsing leaflet.

The apparatus disclosed by Gabbay is adapted for attachment to the annulus of a heart valve. Gabbay teaches that the apparatus includes a base portion which is attached to the valve annulus for providing support at the annulus. However, nowhere in the specification does Gabbay disclose or teach attaching the apparatus to a valve leaflet. As such, Gabbay fails to anticipate or make obvious the claimed subject matter. Accordingly, withdrawal of the rejection and allowance of claims 1, 5, 6, and 15 are respectfully requested.

**REJECTIONS UNDER §103**

Claims 13 and 15 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Streeter (US 2002/065554). For at least the reasons provided above, claims 13 and 15 are also patentable over Streeter.

Finally, claim 14 has been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Gabbay (US 6,419,695) in view of Frey (US 5,607,469). As claim 14 has been canceled, this rejection has been rendered moot.


**CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number MSSM-001.

Respectfully submitted,  
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